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10/575,562	04/12/2006	Masato Shirai	KUZ0029US.NP	1387

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EXAMINER

ORWIG, KEVIN S

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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09/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,562	SHIRAI ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendments filed on Jul. 7, 2009 have been entered.

Status of the Claims

Claims 1-3 and 5-9 are pending. Claims 1 and 7 have been amended; claim 4 is cancelled; claims 8 and 9 have been added. Claims 1-3 and 5-9 are now under consideration. This Office Action is in response to the request for continued examination filed on Jul. 7, 2009.

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to claim 1 is withdrawn in light of the claim amendments.

The rejection of claims 1-3, 5, and 6 under 35 U.S.C. 103(a) over LIPMAN, YANO, and TABAR is withdrawn in light of the claim amendments.

The rejection of claims 1 and 7 under 35 U.S.C. 103(a) over LIPMAN and KUNIYA is withdrawn in light of the claim amendments.

The rejection of claim 4 under 35 U.S.C. 103(a) over LIPMAN and KUNIYA is moot in light of the claim cancellations.

NEW GROUNDS OF REJECTION

New grounds of rejection are presented for claims 1-3 and 5-9.

Claim Objections (New)

Claim 7 is objected to because of the following informalities: claim 7 depends from any one of several claims, including cancelled claim 4. Cancelled claim 4 should be removed from the list of claims from which claim 7 depends.

Appropriate correction is required.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1611

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 7 and now applied to claims 2, 3, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over LIPMAN (U.S. 2004/0243042; Filed May 20, 2003; of record in the prior Office Action) in view of KUNIYA (U.S. 2002/0045043; Published Apr. 18, 2002; of record in the prior Office Action), and Lipman (U.S. 6,326,421; Issued Dec. 4, 2001) (hereinafter '421) as evidenced by YANO (U.S. 5,556,636; Issued Sep. 17, 1996; of record in the prior Office Action), TABAR (U.S. 4,419,480; Issued Dec. 6, 1983; of record in the prior Office Action).

A large body of literature exists regarding pressure-sensitive adhesive compositions comprising the components claimed in instant claim 1. For instance, it is well known that plasters and other medical adhesives are commonly prepared from, *inter alia*, styrene-isoprene-styrene block copolymers, polyisobutylene, and polyisoprene, and that tackifiers and other softening agents are added to impart a

Art Unit: 1611

pressure-sensitive adhesion property to these compositions (see Yano col. 1, lines 21-34). Thus, each of the components recited in claim 1 was well-known in the art at the time of the invention.

1. Lipman discloses compositions comprising pressure-sensitive adhesives (abstract; paragraphs [0034] and [0035]). Lipman teaches adhesive compositions comprising high molecular weight polyisobutylene (i.e. solid polyisobutylene) (paragraph [0051]; Table at bottom of p. 10 and top of p. 11) along with polyisoprene and styrene-isoprene-styrene (SIS) copolymers (Table at bottom of p. 10 and top of p. 11, wherein Kraton D-1161 is a SIS copolymer). Additionally, the adhesive compositions taught by Lipman comprise a liquid rubber component (paragraphs [0009] and [0051]) and a tackifier (paragraph [0070]). The liquid rubber component may be a low molecular weight polyisobutylene (paragraph [0070], see page 7, left col., lines 1-3).

2. Lipman teaches the components of the adhesive compositions in the proportions claimed in instant claim 1. For instance, the adhesives of Lipman are present in an amount from about 10% to 80% of the composition (paragraph [0033]). It is noted that the adhesives can be *one or more* of, *inter alia*, polyisoprene, styrene-isoprene-styrene polymers, and polyisobutylene (paragraph [0034]). Relative to 100% total weight of the composition, the percentages taught by Lipman represent "parts" (e.g. 1% equals 1 part). Based on this evidence and reasoning, Lipman teaches each of polyisoprene, styrene-isoprene-styrene, and polyisobutylene (i.e. solid polyisobutylene) in proportions that may be from about 10% to 80% of the composition (i.e. 10-80 parts). For instance, the teachings of Lipman indicate that these components may be present in amounts, for

Art Unit: 1611

example, of 10 parts polyisoprene, 20 parts styrene-isoprene-styrene copolymer, and 30 parts solid isobutylene (paragraphs [0034] and [0051]).

3. Lipman also teaches the inclusion of liquid polyisobutylene (paragraph [0070]) in a range from 1-30 parts relative to the total of the other three components. Specifically, Lipman states that the adhesive:

"may include one or more optional ingredients such as liquid rubbers, low molecular weight polyisobutylene, high molecular weight polyisobutylene, etc. These materials are each present in an amount from about 1% to about 35%, or from about 2% to about 25%, or from about 3% to about 15% by weight of the adhesive composition." (see paragraph [0051])

4. Thus, the isobutylene could be present in an amount of 10% (i.e. 10 parts), for example. In this case, 10 parts liquid isobutylene corresponds to about 17 parts relative to the other three components when they are present in the proportions discussed above (e.g. 10 parts polyisoprene, 20 parts styrene-isoprene-styrene copolymer, and 30 parts solid isobutylene, for a total of 60 parts). Lipman also teaches the use of tackifiers, but does not disclose the useful range in which tackifiers could be added to the composition.

5. The difference between Lipman and instant claim 1 is that Lipman does not exemplify the tackifier in a proportion of 10-80 parts by weight.

6. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine all the ingredients as instantly claimed based on the teachings of Lipman to produce the instant invention. As noted above, each of the instantly claimed components of the adhesive composition is well known in the adhesive arts. Furthermore, Lipman teaches that the polyisoprene,

Art Unit: 1611

styrene-isoprene-styrene copolymer, and isobutylene adhesive components are equivalent and interchangeable (paragraph [0034]; see table at bottom of p. 10 and top of p. 11, wherein each of the claimed adhesive components are used, often in combination, to prepare an adhesive composition for the same purpose).

7. Furthermore, Kuniya discloses pressure-sensitive adhesive compositions comprising a solid rubber component and a liquid rubber component (abstract). The adhesive composition of Kuniya comprises components of instant claim 1, including styrene-isoprene-styrene copolymers (paragraphs [0016] and [0017]) in combination with other isoprene polymers, such as styrene-isoprene copolymers, which are a type of polyisoprene (paragraph [0018]). Kuniya further teaches the use of a liquid rubber component such as polyisobutylene (paragraph [0019]) and tackifiers (paragraphs [0021] and [0022]).

8. Kuniya teaches the inclusion of the tackifier in an amount from 25-80 parts by weight based on the total amount of the other rubber components in the adhesive composition (abstract). Kuniya teaches that using a high proportion of tackifier improves the adhesion force of the composition (paragraph [0009]). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a high proportion of tackifier in the compositions taught by Lipman, in order to improve the adhesive force of the composition as taught by Kuniya, rendering claim 1 obvious. One would have had a high expectation of success in increasing the amount of tackifier in the adhesive composition in view of '421, also to Lipman, which discloses pressure sensitive adhesives comprising a SIS copolymer, a tackifying resin, and a low-

Art Unit: 1611

MW polyisobutylene, optionally modified by butyl rubber such as a high-MW polyisobutylene (abstract; col. 5, lines 36-38). Lipman teaches that the weight ratio of solid rubber to tackifier is about 1:0.5 to about 1:7 and is varied in order to obtain the desired degree of adhesiveness and tackiness (col. 5, lines 26-28). Thus, in considering the prior art as a whole, the artisan would have expected success in increasing the amount of tackifier in Lipman given Lipman's very own teachings.

9. It is noted that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See MPEP § 2144.06. Furthermore, the MPEP states that the selection of known materials based on their suitability for their intended uses is also *prima facie* obvious. See MPEP § 2144.07. In the instant case, applicants are claiming a combination of known ingredients for the same purpose as that which has been taught in the art. Thus, in light of the teachings of Lipman, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine all the ingredients as instantly claimed based on the teachings of Lipman, using no more than routine optimization to produce an adhesive composition.

Art Unit: 1611

10. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11. The high molecular weight polyisobutylene taught by Lipman (paragraph [0108]) has a viscosity average molecular weight of not less than 900,000 (see Tabar col. 8, lines 30-35), rendering claim 2 obvious.

12. Lipman discloses two embodiments wherein the low molecular weight polyisobutylene has a viscosity average molecular weight of not more than 70,000 (paragraph [0061]), rendering claim 3 obvious.

13. Lipman teaches the use of tackifiers resins including, *inter alia*, rosin, terpene, and phenol types (paragraph [0070]), rendering claim 5 obvious.

14. Lipman allows for the inclusion of active ingredients in the adhesive (antimicrobial compounds are specifically mentioned) (last two sentences of paragraph [0070]) and teaches that the adhesive layer further comprises at least one moisturizing agent (paragraph [0088]; claim 15). These agents include percutaneously absorbable compounds such as squalene and lecithin (paragraph [0088]). Squalene, for example, is a known skin-penetrating agent that can be used to treat various skin disorders such as dry skin, psoriasis, and eczema. Thus, these agents can be considered drugs as defined in the instant specification (paragraph [0030]), rendering claim 6 obvious.

Art Unit: 1611

15. While Lipman teaches the pressure-sensitive adhesive composition adhered to a fluid absorbing layer and a moldable adhesive layer (paragraph [0092] and Figure 4), Lipman does not teach the adhesive composition laminated on a backing and covered with a liner.

16. Kuniya teaches laminating the adhesive composition of their invention to a backing film (paragraph [0014]; claim 7), which may be one of a plurality of such films (paragraph [0028]). Furthermore, Kuniya teaches that the backing may be lined with polypropylene tape (i.e. a liner) (paragraph [0054]). As stated above, Lipman teaches applying the adhesive composition to a backing (paragraph [0092]; figures 4 and 5). In light of the teachings of Kuniya, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to laminate the adhesive composition of Lipman onto a backing, which is covered by a liner. One would have been motivated to do so to produce a marketable final product with the adhesive protected by the release liner until use, as is conventional in the art, rendering claims 7 and 9 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention

Art Unit: 1611

as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipman in view of Kuniya and '421 as evidenced by Tabar as applied to claims 1-3, 5-7, and 9 above, and further in view of YANO (U.S. 4,421,737; Issued Dec. 20, 1983).

17. The teachings of Lipman, Kuniya, and '421 are presented *supra*. While Lipman allows for the addition of optional active agents, none of Lipman, Kuniya, or '421 teach the use of any of the drug classes instantly recited in claim 8.

18. However, adhesives containing various drugs are commonplace in the art and the choice of a particular drug would be routine for a skilled artisan based on the intended use of the composition. For example, Yano discloses a sticky (i.e. adhesive) composition for medical use and transdermal drug delivery (abstract). Yano teaches that adhesives such as those described by Lipman are traditionally applied to the body to treat skin lesions or transdermally deliver drugs to internal lesions or the circulatory system and other organs (col. 1, lines 21-23). Yano teaches the inclusion of a variety of transdermal drugs including, *inter alia*, antibiotics analgesics, NSAIDS, antihistaminics, coronary vasodilators, diuretics, antitussives, anesthetics, antifungals, and steroids.

19. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include such agent(s) in the composition of Lipman. One would have been motivated to do so with a high expectation of success since Lipman allows for the inclusion of active agents and since

Art Unit: 1611

Yano teaches that adhesive compositions are conventionally used to transdermally deliver drugs. Based on the desired condition to be treated, the artisan would have been motivated to select any one of the active agents taught in the art. Claim 8 is obvious over the prior art.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Lipman does not teach the inclusion of liquid polyisobutylene in the instantly claimed range (response, p. 8).

This argument is without merit. As discussed in the rejection above, Lipman states that the adhesive may include one or more optional ingredients such as liquid rubbers, low molecular weight polyisobutylene, high molecular weight polyisobutylene, etc. These materials are each present in an amount from about 1% to about 35%, or from about 2% to about 25%, or from about 3% to about 15% by weight of the adhesive composition (paragraph [0051]). Thus, the reasoning and example set forth in the previous Office Actions (i.e. the use of liquid polyisobutylene in an amount of 10%) is completely in line with Lipman's disclosure. It is acknowledged that Lipman does not embody compositions having this percentage of liquid polyisobutylene, but the examples do not negate Lipman's teaching of amounts of about 1-35% for this component.

Applicants argue that Lipman teaches away from the inclusion of tackifiers in the instantly claimed range (response, p. 9) and that using higher amounts of tackifiers in Lipman's composition would render it unsatisfactory for its intended purpose.

Art Unit: 1611

Applicants admit that Lipman discloses no numerical range for the tackifiers in the invention (see response, p. 9). Furthermore, Lipman specifically states that the disclosed examples are non-limiting. Thus, an artisan would be motivated to look to the literature for guidance as to the workable range of tackifier in the composition and would not think that the examples provided by Lipman were intended to limit the amount of tackifier added. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). As discussed above, one of Lipman's own patents ('421) discloses the use of higher amounts of tackifier in adhesive compositions substantially similar to those of Lipman's later work.

Applicants refer to the statement made by Lipman that, "...tackifiers used in prior art hydrocolloid adhesives may make the present composition too sticky." Applicants appear to rely on this single statement to support the assertion that Lipman teaches away from the use of higher amounts of tackifier. This statement does not specify that any certain amount of tackifier will make the compositions "too sticky" as suggested by applicant. Rather, Lipman is stating that prior art tackifiers (i.e. tackifiers not disclosed by Lipman) may be unsatisfactory. Since Lipman teaches that tackifiers may be added to the adhesive composition to modify the tack and optimize the adhesion properties, it is clear that the tackifiers disclosed by Lipman are acceptable in Lipman's compositions (paragraph [0070]). Since Lipman is silent to the useful range of this component the skilled artisan would look to the literature and would expect to optimize the amount of the tackifier based on Lipman's teaching.

Art Unit: 1611

Regarding applicant's assertion that higher amounts of tackifiers render the composition unsatisfactory for its intended purpose, there is no evidence of record to support this assertion. Lipman does not specify an upper limit to the tackifier, as admitted by applicants, and thus cannot possibly teach that increasing the amount of tackifier beyond those in Lipman's non-limiting examples renders the adhesive composition unsatisfactory. Furthermore, '421 establishes that substantially identical adhesive compositions can contain higher amounts of tackifier. Kuniya teaches that using a proportion of tackifier in the range of 25-80 parts by weight based on the total amount of the other rubber components improves the adhesion force of the composition (paragraph [0009]). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a high proportion of tackifier in the compositions taught by Lipman, in order to improve the adhesive force of the composition as taught by Kuniya.

Conclusion

Claims 1-3 and 5-9 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1611

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643